TOX/2020/50

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Update on alternatives to conventional plastics for food & drinks packaging

Background and Introduction

1. In May 2020, a paper entitled "*Scoping paper: alternatives to conventional plastics for food & drinks packaging* (TOX/2020/24[1])" was presented to the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). The paper was based on the Fera Science[2] report (2019) "*Bio-Based Materials For Use In Food Contact Applications*" [3] (ANNEX A) commissioned by the Food Standards Agency (FSA).

2. Key findings from the Fera report were:

- Limited research has been undertaken into the development of bio-based food contact materials (BBFCMs) derived from agri-food by-products, and the associated risks to the consumer.

- BBFCMs can exhibit barrier properties similar to traditional fossil-based plastics enabling comparable shelf life performance and consumer protection.

- Information on the presence of inorganic contaminants such as heavy metals, persistent organic contaminants and natural toxins in BBFCMs, and their capacity to transfer from biomass-derived BBFCMs into food, is required.

- Polypeptide-based materials[4] used for packaging may include substances that are known or suspected allergens or are extracted from matrices that contain allergens. The effects of processing to produce packaging materials may alter allergenicity in unpredictable ways, depending on whether the allergenic epitopes are destroyed or revealed, for example due to conformational changes of the polypeptides. Very limited information is available on the allergenicity of BBFCMs as well as the potential for transfer of allergens to food.

[1] https://cot.food.gov.uk/sites/default/files/2020-08/tox202024plasticpackagingalternatives_accessibleinadobepro_0.pdf
[2] https://www.fera.co.uk/
[3] https://www.food.gov.uk/sites/default/files/media/document/bio-based-materials-for-use-in-food-contact-applications_0.pdf
[4] A polypeptide is a linear organic polymer consisting of a large number of amino-acid residues bonded together in a chain, forming part of (or the whole of) a protein molecule.

- Current analytical methods and risk assessment processes for establishing contaminant chemical transfer from fossil-based plastics to food are expected to be appropriate for or adaptable to BBFCMs.

3. The Committee was asked to provide further guidance on the potential toxicological hazards associated with BBFCMs and to prioritise a list of BBFCMs to review in further detail.

4. Members noted that quantitative information was needed on contamination, degradation, and migration of chemicals and allergens during the manufacture of commercial BBFCMs, as well as environmental impacts after disposal, for example formation of micro/nano-plastics upon entering landfill or from energy-from-waste processes. Numerous papers discussed the presence of nanomaterials in BBFCMs, however there was a general lack of toxicological information on such materials[5].

5. The Committee was also asked to advise on which BBFCMs require consideration in further detail. Due to the diversity of available BBFCMs for industrial use, the Committee agreed that, in addition to policy pririties, it would be helpful to focus on BBFCMs that are most or most likely to be used in the UK, either directly or through import, such as polylactic acid (PLA) plastic. The Secretariat agreed to identify the most widely used materials and other higher priority materials for further review.

6. To address the above, in this update the Secretariat have identified some recent reports and scientific literature which answer some of the questions from the COT.

Update from cross FSA teams: Policy & Surveillance

7. In the interim period, the Food Contact Materials (FCM) Policy team at the FSA added that they have received enquiries on BBFCMs such as chitin-based BBFCMs and chitosan-based drinking straws regarding their allergenic content. The nature of these enquiries is presented in Table 1.

8. In order to address the issue of allergenicity of chitin and chitosan-based BBFCMs a discussion paper focussing on the immunogenicity and allergenicity of chitin- and chitosan-based BBFCMs was taken to COT in September 2020 (TOX/2020/42[6]).

9. Members agreed that the risk of allergenicity and immunogenicity from these products is not expected to be at levels that may be of health concern, however further data on protein characterisation, migration into food and exposure are required to perform a more comprehensive health risk characterisation and risk assessment.

[5] https://cot.food.gov.uk/sites/default/files/2020-08/10072020finalmayminutes.pdf
[6] https://cot.food.gov.uk/sites/default/files/2020-09/TOX-20-42%20Chitosan%20%26%20chitin%20BBFCMs.pdf

Computational tools

10. Computational tools currently being developed internally with in house data scientists within the FSA will provide up to date information on various facets of BBFCMs including hazards and trends. The output of these tools will be internally reviewed periodically and when necessary presented to the COT on an *ad hoc* basis. An example using bamboo data is shown in ANNEX B.

Table 1: Breakdown of bio-based and composite FCMs that FSA Policy has received enquiries on (until September 2020).

Bio-based material **Either the polymer or the material**	**Commodity**	**The number of businesses identified via direct queries to FSA**	**The number of businesses identified via online searches or another source**	**UK Incidents**
Bamboo (generally a composite with melamine) Bamboo/wood pulp	• Kitchenware/ Tableware predominantly • Drinking straws	Bamboo has been used for several years. We have received more than a dozen queries over recent years.	Large number of businesses producing bamboo products	Large volume of tableware/kitchenware sets have been involved in UK incidents. The top incident has been identified as formaldehyde (ANNEX B).[7]
Chitosan (typically derived from shellfish/fish waste)	• Packaging and food films (primary and secondary packaging) • Drinking straws	4 3	1 1	None raised formally although one report of a potential reaction to the use of a chitosan-based straw in a pub was reported to a local authority. It was concluded that the reaction was a result of the meal, however additional precautions were put in place concerning labelling. Several pub chains have switched to using chitosan-based straws but are required to include clear labelling.
Wheat	• Cups/Mugs • Drinking straws	0 2	3 6 (*N.B.* Stroodles pasta straws do advise an allergy alert for gluten on website).	Not aware of any.

[7] German institute for risk assessment publishes position statement on melamine-formaldehyde resins, including tableware made with bamboo fibres; warns consumers against using such tableware with hot liquids; recommends lowering specific migration limit of formaldehyde in EU regulation from 15 to 6 mg/kg. BfR statement on bamboo cups and tableware

Avocado Seed (composite)	• Standard utensils using drinking straws.	1 (Patent)	0	Not aware of any.
Rice husk/straw (composite)	• Cups • Kitchenware/ Tableware	0 0	4 2	Not aware of any.
Alginate (typically derived from Seaweed)	• Pouches • Films	0 0	1 1	Not aware of any.
Cellulose (Grass)	• Drinking straws	0	1 (includes Bullrush stems)	Not aware of any.
Eucalyptus	• Primary packaging	0	1	
Bagasse (Sugar Cane)	• Tableware (plates)	0	3	Not aware of any.
Starch (derived from potatoes and corn)	• Films • Drinking Straws	0 0	1 1 *(with 20% plastic)	Not aware of any.
Beeswax	• Food wraps (primary packaging)	A large number of queries, including directly from LAs.	Large number of businesses producing beeswax wraps. Many are small businesses using locally sourced beeswax.	Not aware of any.
PLA	• Cups • Drinking straws	0	Many producers of these types of products.	Not aware of any.
Coconut shells	• Bowls	0	1	Not aware of any.
Peanut shells				Not aware of any.
Coir (Coconut fibre)				Not aware of any.

Bioplastic Market Data and Development and Consumer Perception

11. The COT asked the Secretariat for information on consumer and market data of BBFCMs. The Secretariat have identified a couple of fact sheet reports by the European Bioplastic Network[8] which outlines the current market data and development in this sector.

European Bioplastic Network Reports

- Materials and market development in the packaging segment[9]
- Bioplastics market data 2019[10]

[8] https://www.european-bioplastics.org/
[9] https://docs.european-bioplastics.org/publications/fs/EUBP_FS_Packging.pdf
[10] https://docs.european-bioplastics.org/publications/market_data/Report_Bioplastics_Market_Data_2019.pdf

12. These reports outline some of the top applications (packaging remains the largest field of application for bioplastics with more than 53 percent (1.14 million tonnes)) and materials types *e.g*. PLA (Figure 1), as well as global production capacities (Figure 2). Biodegradable plastics altogether, including PLA, Polyhydroxyalkanoates (PHA), starch blends and others, account for over 55.5 percent (over 1 million tonnes) of the global bioplastics production capacities (Figure 3 and Figure 4). The production of biodegradable plastics is expected to increase to 1.33 million in 2024 especially due to PHA's significant growth rates.

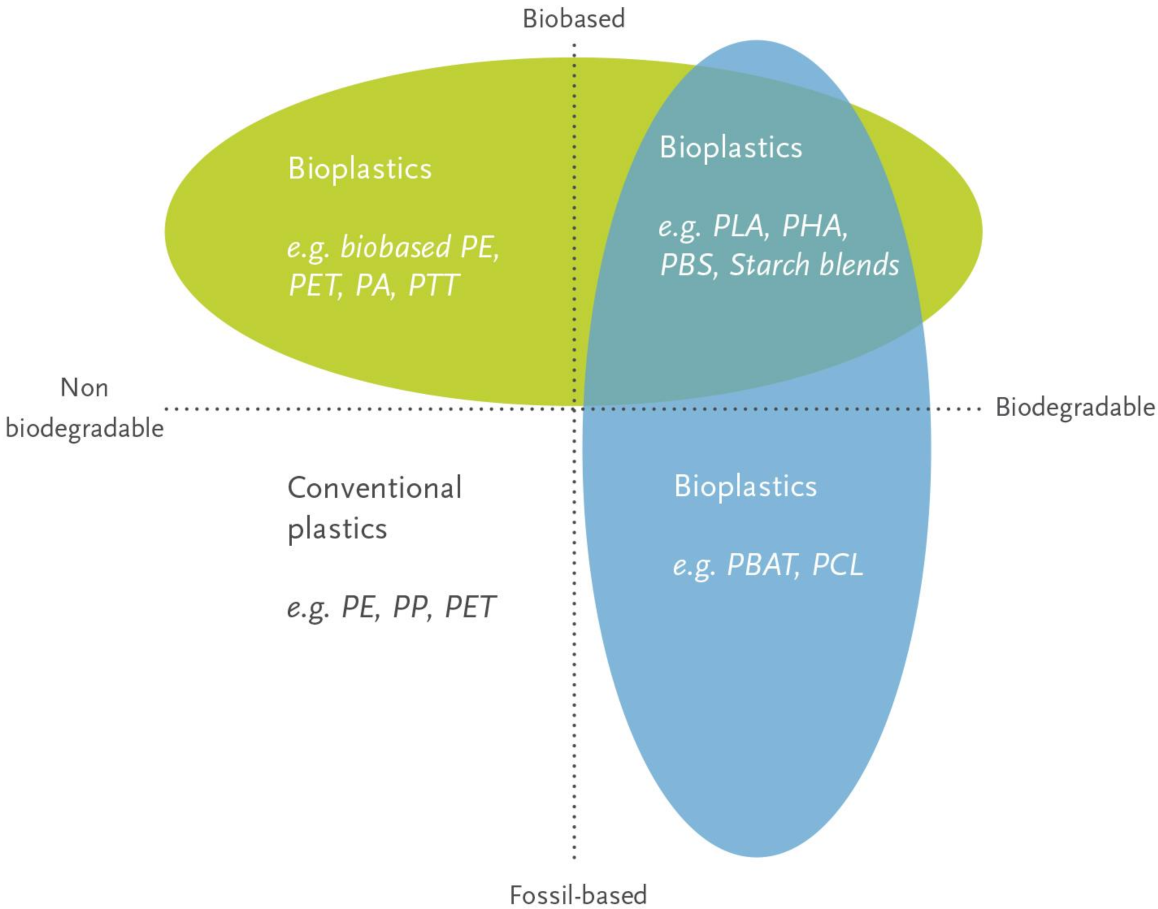
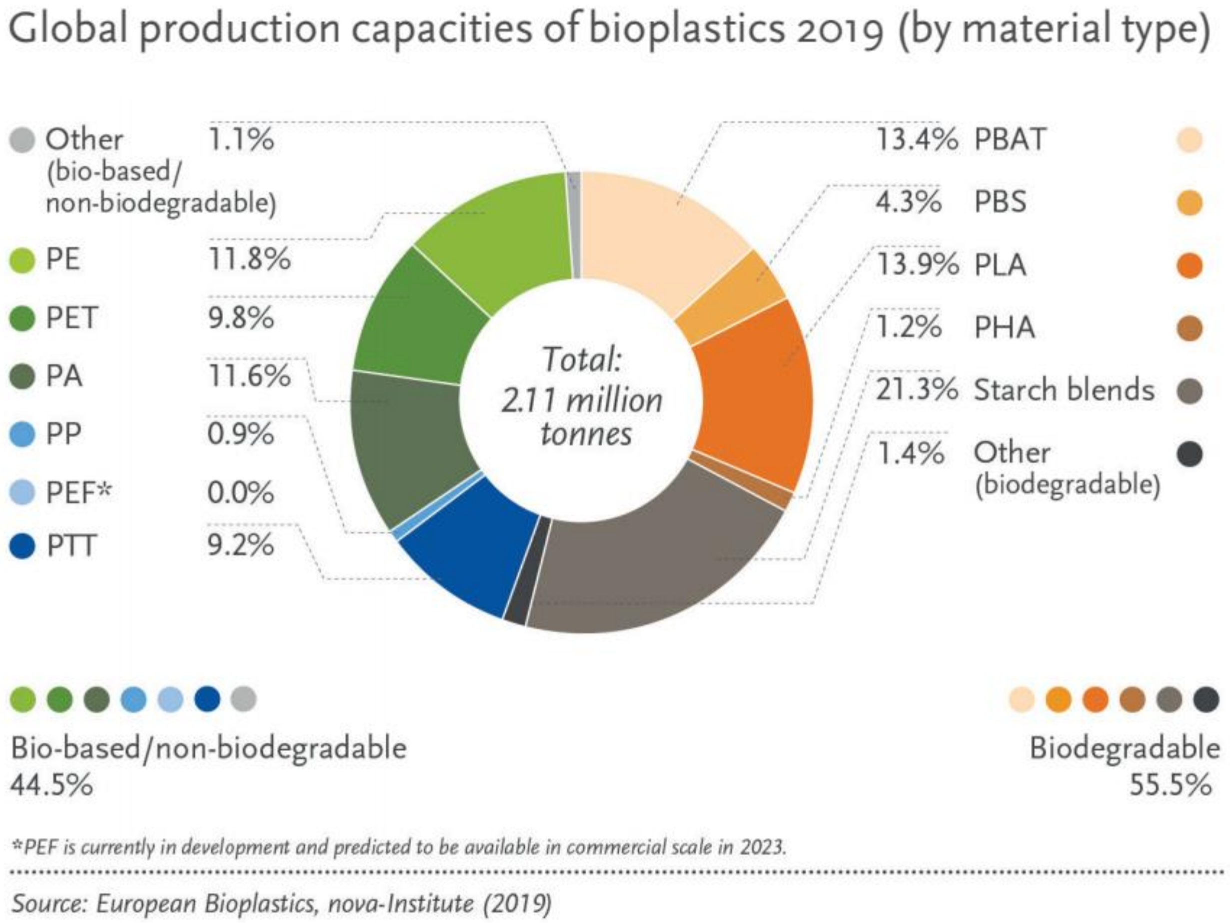


Figure 1. Diagram showing bioplastics are a diverse complex set of materials and blends. There are three main groups: Biobased or partially biobased non-biodegradable plastics and biobased technical performance polymers; plastics that are both biobased and biodegradable; plastics that are based on fossil resources and are biodegradable, such as PBAT (reproduced from European Bioplastics Network website[11]).

[11] https://www.european-bioplastics.org/bioplastics/materials/



Key
PE: Polyethylene; PET: Polyethylene terephthalate; PA: Polyamide;
PP: Polypropylene; PEF: Polyethylene Furanoate; PTT: Polytrimethylene terephthalate;
PBAT: polybutylene adipate terephthalate PLA: polylactic acid; PHA: Polyhydroxyalkanoates

Figure 2. Global production capacities of bioplastics 2019 (by materials type) (reproduced from European Bioplastic Market Data Report[12]).

[12] https://docs.european-bioplastics.org/publications/market_data/Report_Bioplastics_Market_Data_2019.pdf

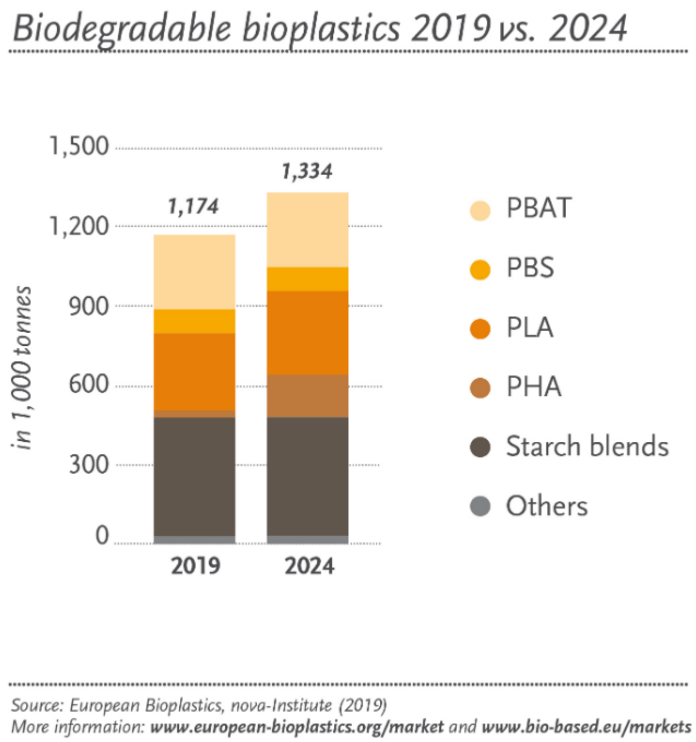


Figure 3. Graph showing biodegradable bioplastics market 2019 versus 2024 (reproduced from European Bioplastics Website[13]).

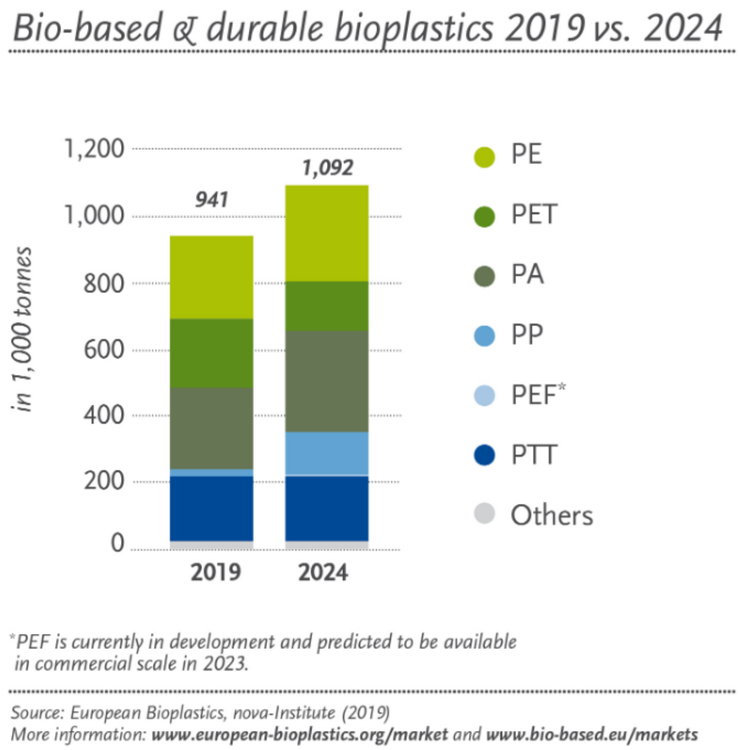


Figure 4. Graph showing biobased & durable bioplastics market 2019 versus 2024 (reproduced from the European Bioplastics Website[14]).

[13] https://www.european-bioplastics.org/bioplastics/materials/biodegradable/
[14] https://www.european-bioplastics.org/bioplastics/materials/biobased/

European Environment Agency Report

13. A report by the European Environment Agency titled "*Biodegradable and compostable plastics challenges and opportunities*"[15] was recently published in which it highlighted the complexities in this field. One of the key findings was that: "Biodegradable, compostable and bio-based plastics need clearer labelling and repeated awareness-raising campaigns targeting users to ensure their correct disposal and treatment".

Update on scientific literature: *In vitro* toxicity of BBFCMs

14. A recent study (Zimmermann *et al*., 2020) used methanol (99.9%) to extract the chemical composition of FCMs as well as their respective raw materials (pre-production pellets): 27 bioplastics with the highest market share[16], including materials that are bio-based and biodegradable (PLA, PHA), petroleum-based and biodegradable (PBS, PBAT) as well as bio-based and not biodegradable, 16 plant-based materials (starch, cellulose, bamboo) and 31 samples which held an inscription to be suitable as FCMs (Table 2). Chemical compositions of the extracts were analysed with non-target high-resolution mass spectrometry. The extracts were characterized using *in vitro* bioassays for baseline toxicity (Microtox bioassay (*Aliivibrio fischeri*) [17]), oxidative stress responses, and oestrogenic and anti-androgenic activity.

Table 2. Bioplastics and plant-based materials analysed in the study and total number of chemicals features detected by ultra-performance liquid chromatography/quadrupole time-of-flight mass spectrometry (UPLC-QTOF-MS/MS). FCM: Indication that material is suitable for food contact (+), Type: Raw material (RM), final product (P).

Plastic category	Sample and plastic type	Plastic product	FCM	Type	Number of detected chemical features
Bio-based, biodegradable	PLA 1	Single-use drinking cup	+	P	3755
Bio-based, biodegradable	PLA 2	Disposable cutlery	+	P	3479
Bio-based, biodegradable	PLA 3	Film	+	P	8648
Bio-based, biodegradable	PLA 4	Food tray	+	P	6465
Bio-based, biodegradable	PLA 5	Coffee capsule	+	P	6121
Bio-based, biodegradable	PLA 6	Bag for foodstuff	+	P	17,224
Bio-based, biodegradable	PLA 7	Single-use bottle	+	P	3002

[15] https://www.eea.europa.eu/publications/biodegradable-and-compostable-plastics
[16] https://www.foodpackagingforum.org/news/in-vitro-toxicity-of-bioplastics-and-plant-based-materials
[17] Microtox is an *in vitro* testing system which uses bioluminescent bacteria to detect toxic substances in different substrates such as water, air, soils and sediments.

Bio-based, biodegradable	PLA 8	Film		P	10,958
Bio-based, biodegradable	PLA 9	Pellet	+	RM	3667
Bio-based, biodegradable	PLA 10	Pellet		RM	880
Bio-based, biodegradable	PHA 1	Pellet		RM	614
Petroleum based, biodegradable	PBS 1	Plastic bar		RM	3864
Petroleum based, biodegradable	PBS 2	Food tray	+	P	10,959
Petroleum based, biodegradable	PBAT 1	Waste bag	+	P	15,843
Petroleum based, biodegradable	PBAT 2	Pellet	+	RM	9161
Plant-based	Starch 1	Disposable cutlery	+	P	1065
Plant-based	Starch 2	Bag for foodstuff	+	P	18,198
Plant-based	Starch 3	Film		P	15,770
Plant-based	Starch 4	Film	+	P	16,857
Plant-based	Starch 5	Pellet	+	RM	9118
Plant-based	Starch 6	Pellet	+	RM	8325
Plant-based	Starch 7	Waste bag	—	P	20,965
Plant-based	Starch 8	Film		P	11,901
Plant-based	Cellulose 1	Tea bag wrapping	+	P	14,456
Plant-based	Cellulose 2	Chocolate wrapping	+	P	3378
Plant-based	Cellulose 3	Cigarette filter	—	P	15,719
Plant-based	Cellulose 4	Pellet	+	RM	2953
Plant-based	Cellulose 5	Bag for foodstuff	+	P	20,416
Plant-based	Cellulose 6	Bag for foodstuff	+	P	14,031
Plant-based	Cellulose 7	Bag for foodstuff	+	P	17,495
Plant-based	Bamboo 1	Reusable coffee cup	+	P	5426
Bio-based, non-biodegradable	Bio-PE 1	Bag for foodstuff	+	P	5272
Bio-based, non-biodegradable	Bio-PE 2	Wine closure	+	P	1629
Bio-based, non-biodegradable	Bio-PE 3	Bag for foodstuff	+	P	n.a.[a]
Bio-based, non-biodegradable	Bio-PE 4	Pellet		RM	819
Bio-based, non-biodegradable	Bio-PE 5	Food tray	+	P	290
Bio-based, non-biodegradable	Bio-PE 6	Film		P	928

Bio-based, non-biodegradable	Bio-PE 7	Wine closure	+	P	947
Bio-based, non-biodegradable	Bio-PE 8	Pellet		RM	186
Bio-based, non-biodegradable	Bio-PE 9	Bag for foodstuff	+	P	19,028
Bio-based, non-biodegradable	Bio-PE 10	Film	+	P	13,381
Bio-based, non-biodegradable	Bio-PET 1	Reusable bottle	+	P	390
Bio-based, non-biodegradable	Bio-PET 2	Box		P	5625

Note: [a] n.a., not analyzed.

15. The authors stated that bio-based/biodegradable materials and conventional plastics were similarly toxic. Results demonstrated two-third (67%) of the samples induced baseline toxicity, 42% oxidative stress, 23% anti-androgenicity and one sample oestrogenicity (Figure 5). It revealed that starch-based and cellulose would induce the strongest *in vitro* toxicity.

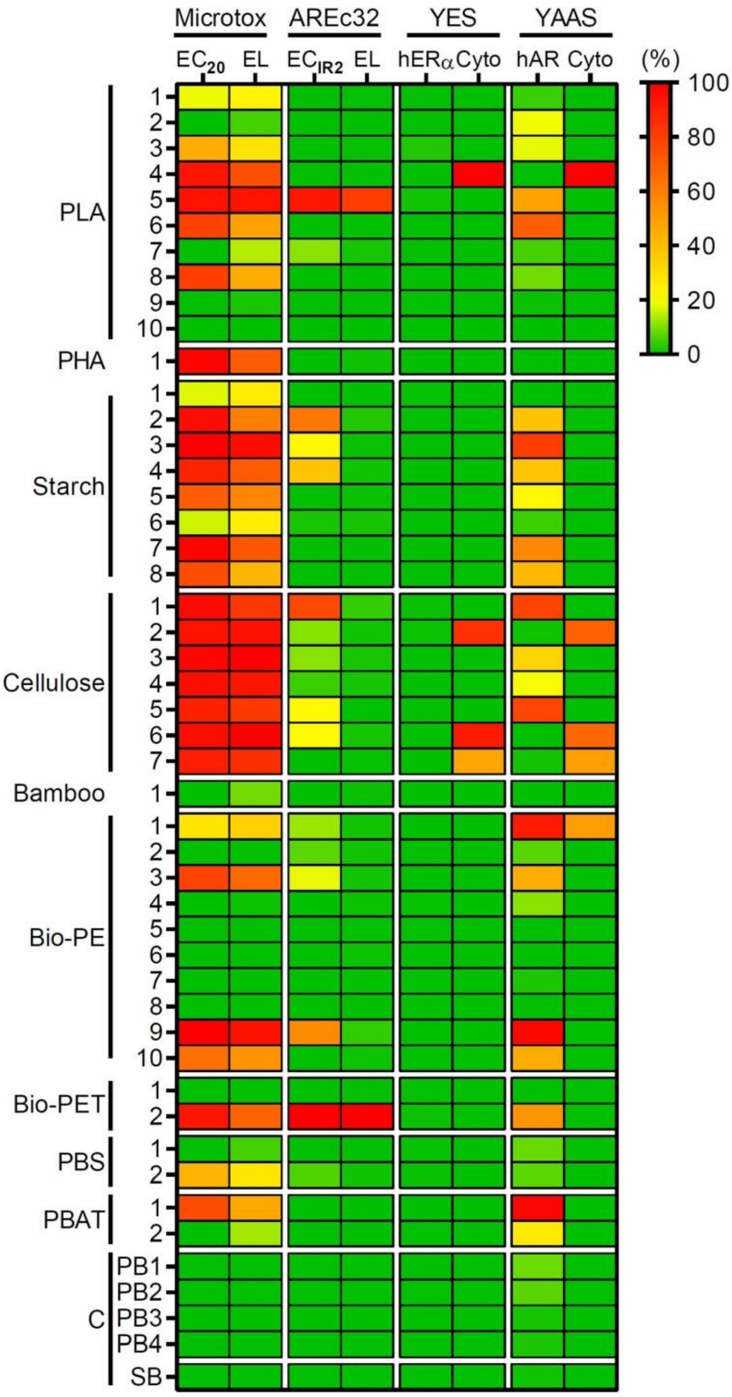
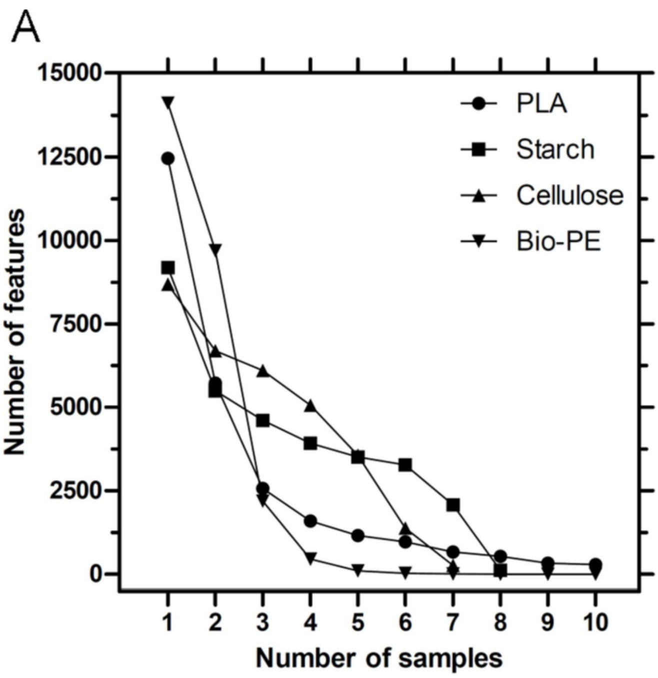


Figure 5. Toxicological signature of bioplastics and plant-based materials based on baseline toxicity (Microtox- according to an International Organization for Standardization (ISO) guideline (ISO 11348-3, 2017), oxidative stress response (AREc32) as well as estrogenic (YES) and antiandrogenic activities (YAAS). The results are presented as effect concentrations (EC20, ECIR2), effect levels (EL), relative receptor activation/inhibition and EC20 for cytotoxicity (Cyto). Results are presented as gradient from 0 (green) to 100% (red) (Data was processed as previously described to derive the relative cytotoxicity as well as relative oestrogenic and antiandrogenic activities (Völker *et al*., 2016)). The endocrine activities were used as such while the other results were normalized to the lowest and highest effect

observed for the respective endpoint. (Figure reproduced from Zimmerman *et al*., 2020).

16. In total, Zimmerman *et al*., (2020) detected 41,395 chemical features in the 41 extracts with 186-20,965 features present in the individual samples (Figure 6). 80% of the extracts contained > 1,000 features, most of them unique to one sample. They identified 343 priority compounds including monomers, oligomers, plastic additives, lubricants and non-intentionally added substances.



B

# feat.	PLA 26,258	PHA 614	Starch 32,164	Cell 31,727	Bam 5,426	Bio-PE 26,566	Bio-PET 5,913	PBS 13,049	PBAT 19,188
PLA	-	1.7	65.5	60.5	18.4	59.6	16.9	42.7	53.6
PHA	437	-	1.6	1.6	2.3	1.8	2.3	1.8	1.8
Starch	23,112	510	-	69.2	16.0	65.5	15.6	38.2	54.3
Cell	21,856	508	26,141	-	15.8	62.9	15.7	36.3	50.2
Bam	4,922	134	5,191	5,063	-	17.9	13.3	21.7	20.7
Bio-PE	19,731	476	23,239	22,500	4,865	-	17.7	39.6	59.1
Bio-PET	4,657	145	5,136	5,094	1,330	4,892	-	16.2	18.5
PBS	11,761	245	12,486	11,926	3,290	11,235	2,646	-	44.3
PBAT	15,856	341	18,067	17,013	4,218	16,995	3,926	9,895	-

Figure 6. Number of chemical features plotted according to the number of samples per material it is detected in (A) and number of features shared between materials (B). In B, features are considered that have been detected in at least one sample per material (sum given as # feat.). The lower left section represents the number of shared features, the upper right section their percentage of all features detected in the combination of materials. (Figure reproduced from Zimmerman *et al* 2020).

17. Toxicity was less prevalent and potent in raw materials than in final products likely due to (compounding) new substances are added or generated. The authors hypothesised that this was due to fewer detected overall chemical features in raw materials than in final products of the same material. The authors concluded that most bioplastics and plant-based materials contain toxic chemicals like their conventional plastics (Figure 7).

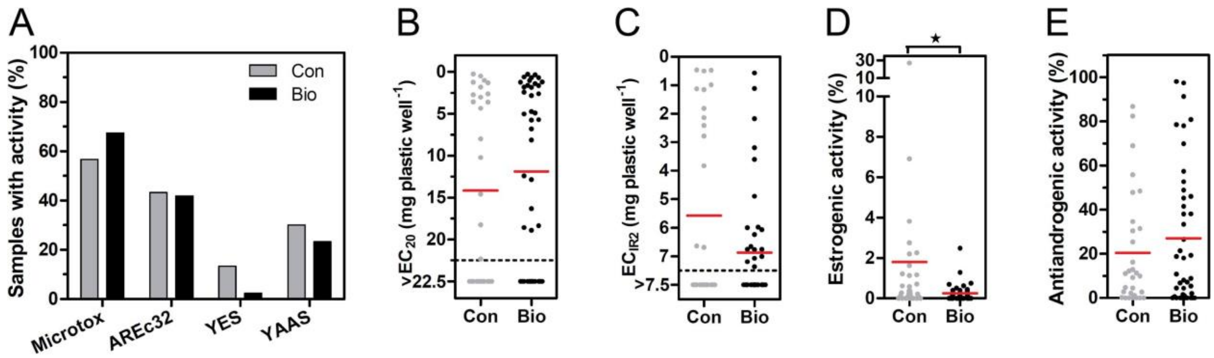


Figure 7. Toxicity of extracts from conventional, petroleum-based (Con, n = 30) compared to bioplastics and plant-based materials (Bio, n = 43) with regards to the percentage of active samples (A) and the mean effect strengths for baseline toxicity (B, Microtox), oxidative stress response (C, AREc32), estrogenic (D, YES) and antiandrogenic activity (E, YAAS). Each dot represents one sample and red lines the mean. For D and E, effects are shown for 3.75 mg plastic well−1 or, if cytotoxic, for the highest non-cytotoxic concentration (Tab. S5). * $p < 0.05$, unpaired Mann-Whitney test, dotted lines = highest analysed concentration. Toxicity data for conventional materials are taken from Zimmermann et al. (2019). (Figure reproduced from Zimmerman *et al* 2020).

Micro and nanosized plastic particles

18. As stated in TOX/2020/24[18] many BBFCMs exhibit biodegradability. Given the fragmentation of larger pieces of bioplastics is inevitable and a fundamental route for degradation, it is possible for bioplastics to form fragments of various sizes and shapes in environments during degradation, including micro and nano sized plastic particles. Members noted that information was needed on contamination, degradation, and migration of chemicals during the manufacture of commercial BBFCMs, as well as environmental impacts after disposal, for example formation of micro/nano-plastics upon entering landfill or from energy-from-waste processes[19].

19. Shruti & Kutralam-Muniasamy, (2019) provided a review on the current knowledge of microplastics and highlights how microplastics from biodegradable plastic materials should be incorporated in ongoing researches. An unstructured literature review was performed using PubMed, Google Scholar, Nature’s database and Science Direct with the keywords “biodegradable microplastics and bioplastics microplastics”. Aquatic degradation experiments (30 days in two different waters of Mexico with different pH values; tap water (where it is generally advised as not being potable; pH:8.3) and drinking water (pH:6.8)) were also performed using PHA films (0.1 g) in order to investigate whether PHA films degrade in a similar manner to conventional plastics in an aquatic environment (*i.e.* the formation of smaller plastic particles).

[18] https://cot.food.gov.uk/sites/default/files/2020-08/tox202024plasticpackagingalternatives_accessibleinadobepro_0.pdf
[19] https://cot.food.gov.uk/sites/default/files/2020-08/10072020finalmayminutes.pdf

20. Samples were then filtered using nitrocellulose filter paper (0.2 µm pore size). The collected material was then studied for shape, size and surface characteristics using field emission-scanning electron microscopy (SEM).

21. Thirty articles were found to act as evidence that microplastics from bioplastics do instigate risks in the various organism models tested. It was concluded by the authors that based on these studies; exposure from conventional and biodegradable microplastics show similar organism effects and how the induced changes can affect both individual fitness within wild populations and ecological processes.

22. The primary degradation morphology of microplastics was deep cracks, fractures and pits. SEM images of PHB microplastics showed rich microbial community developing on their surface. A mixture of sizes was observed including macro (<5 mm), micro (100–1600 µm) and nanoplastics (<100 µm). Several knowledge gaps were identified by the authors including the lack of:

- Documentation on disintegration and degradation behaviour of bioplastics to micro- and nanoplastics;
- Studies to demonstrate less persistence and ensuring degradability of bioplastics in environmental conditions;
- Toxicity tests and potential effects on a wide variety of organisms;
- Assessments on impacts on ecosystems and;
- Evaluation between the interaction of micro-organisms and microplastics.

23. The COT is currently reviewing information on the potential health effects of microplastics (TOX/2020/40)[20]. The Secretariat will update the COT when more information becomes available on biobased plastic particles.

Other recent reports and information

Standardisation

24. The European Commission is in development to establish several standards for the biobased industry to harmonize methodologies and technologies. The standards for bio-based are and have been developed by the CEN/TC 411 committee on "*Biobased products*"[21]. These standards include details on determining bio-based content, sustainability criteria and Life Cycle Assessment[22].

Migration

25. The COT discussed the lack of migration levels of chemicals found in BBFCMs. Members are referred to an internal FSA research (A03070) carried out by

[20] https://cot.food.gov.uk/sites/default/files/2020-09/TOX-2020-40%20Annex%20A%20Microplastics%20overarching%20statement_0.pdf
[21] https://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_ORG_ID:874780&cs=112703B035FC937E906D8EFA5DA87FAB8
[22] Life-cycle assessment or life cycle assessment is a methodology for assessing environmental impacts associated with all the stages of the life-cycle of a commercial product, process, or service.

The Food and Environment Research Agency (FERA) (now Fera Science Ltd) in 2010, on biobased materials used in food contact applications and an assessment of their migration potential (Bradley, 2010)[23].

26. Briefly, thirteen packaging materials tested there was little measurable migration into food simulants and foods. Where migration was observed, the simulants defined in the legislation (for plastics) overestimated or provided a good approximation to the migration into foods.

27. Exposure to water and other aqueous simulants altered the appearance of several of the samples included in this project. Therefore, the limitation of these material types in terms of their ability to maintain their shape and perform their function should be recognised and it is recommended that materials and articles should be labelled to define the contact conditions for which they will function.

28. The Food Packaging Forum previously published a dossier on bioplastics as food contact materials (Geueke, 2014)[24], where migration and human health effects were discussed. During their search migration studies were mainly associated from PLA and starch-based polymers. Migration of lactic acid, its dimer, and lactide from PLA were reported to be low, and under consideration of the toxicological data the authors concluded that PLA is a substance Generally Recognized As Safe (GRAS)[25,26].

29. In this review, it was highlighted that further aspects of migration should be addressed to investigate and evaluate:

- The different physico-chemical properties of biobased FCMs might result in higher or lower migration rates of additives compared to fossil-fuel based materials. Theoretical models covering these aspects would be desirable;
- The potential migration of additives and stabilisers since bioplastics are usually less stable and have a lower diffusion barrier than conventional plastics and how these levels compare to conventional plastics and;
- For cellulose- and starch-based polymers the migration of glucose may also be a cause for concern.

30. Another review (Scarfato *et al*., 2015), describes the most recent advances and emerging technologies in food-packaging applications of biodegradable plastics from renewable sources.

31. The reviewed literature primarily focused on novel formulations to overcome the limitations of such biopolymers, in terms of the processability, stability, and

[23] Bradley, E. L. (2010) FSA PROJECT A03070 Biobased materials used in food contact applications: an assessment of the migration potential. Available at: https://www.food.gov.uk/sites/default/files/media/document/a03070.pdf
[24] Geueke, B. (2014) Dossier – Bioplastics as food contact materials. Available at: https://www.foodpackagingforum.org/fpf-2016/wp-content/uploads/2015/11/FPF_Dossier06_Bioplastics.pdf.
[25] A GRAS determination can be self-affirmed or the FDA can be notified of a determination of GRAS by qualified non-governmental experts.
[26] https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras

structural and functional performance, based on the addition of other substances, such as micro sized and nanosized fillers and plasticizers.

32. These formulations have been demonstrated to improve several properties of technological interest, mainly the diffusion barrier against the permeation of low molecules, such as water and oxygen, without unacceptable detrimental effects toward the migration of undesirable substances from the polymer matrix in most cases.

33. However, the authors stated that most of these studies were only limited to the evaluation of the overall migration and were conducted with food simulant solvents. The testing with real foodstuffs and the knowledge of the effect on human health and risk assessments are largely insufficient, especially when nanosized additives are contained in the biopolymer formulation.

34. It also stated that, in Europe, biodegradable plastics for food-contact applications are regulated in the same manner as conventional plastic materials under Commission Regulation EC 10/2011 on plastic materials and articles intended to come into contact with food. The regulation sets down the safety requirements of plastic materials by giving general provisions and compositional requirements, listing all the substances authorized in the manufacturing of conventional and biodegradable plastics (Annex I) and describing in detail the testing of overall and specific migration (Annex V)[27].

35. However, because pure biopolymers are in general less stable and have a lower diffusion barrier than conventional polymers, more additives are usually used in biodegradable plastics. Therefore, some undesirable interactions and consequent migration of substances may be more or less frequent for one than for the other.

36. Nevertheless, few studies concerning the safety assessment of food packaging made of biodegradable polymers by migration testing have been reported in the literature.

Recent advances and emerging technologies in food-packaging applications

37. The main trend driving research is the development of new and better performing biodegradable systems, often through material modifications or additions. Even in conventional plastics the use of nanotechnology[28] to enhance safety and to increase shelf life is being used (Enescu *et al*., 2019). It is being used as a source of key improvements for the current challenges in food security and food sustainability.

38. A recent review by Halonen *et al*., (2020) explores the state-of-the-art of bio-based polymers used as food contact materials and the potential use of natural compounds for sensing chemical and physical changes of the environment to monitor the food quality.

[27] European Commission. Off. J. Eur. Commun. 2011, L12,1 (Available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0010)
[28] Nanotechnology is the use of matter on an atomic, molecular, and supramolecular scale for industrial purposes.

39. It consisted of key components of bio-based smart materials:

- Bio-based smart food packages: Smart functionalities of food packages refer to active coatings and physical/chemical sensors combined with the packaging materials. The purpose of smart antimicrobial coatings is to mitigate the proliferation of various microbes thus prolonging the shelf-life of products.

- Bio-based sensors: these are sensors have at least one component from bio-based source which may either be the substrate or the sensing element such as starch or chitosan. Sensors play role in monitoring physical and chemical conditions that influence or reflect the quality of the food products.

Limitations and knowledge gaps

40. There is still several limitations and knowledge gaps in the BBFCMs research and regulation space. Specifically, more conclusive results to ensure that the safety of this kind of packaging materials in direct food-contact applications meets standards like in conventional plastics including labelling of content. Overall and specific migration of all the possible migrating substances (nanofillers, plasticizers, antimicrobial additives, micron and nano sized plastic particles *etc*.) under different testing conditions to obtain exposure data and to demonstrate that these novel biodegradable packages meet the legal requirements. Furthermore, toxicity studies including long term / *in vivo* will ensure a more comprehensive risk assessment.

Summary and future

41. In this update the Secretariat have identified some recent reports and scientific literature to answer some of the questions the COT put forth at previous meetings.

42. In addition, the FSA FCM Policy Team has provided a table of enquiries regarding BBFCMs (*Table 1*).

43. Market data and consumer perception data has shown the differential complexities as well as different materials that make up the BBFCM industry and potential future use percentage (*Figs. 1-4*).

44. There are still several limitations and knowledge gaps in the BBFCMs research and regulation space including migration levels. Furthermore, we are starting to see scientific research into the potential health effects. The Secretariat will keep updating the COT when more information becomes available.

Questions to the committee

45. Members are invited to consider the following questions and to raise any other matters that arise from the newly submitted data:

i) Can the Committee provide further guidance on the potential toxicological hazards associated with BBFCMs?
ii) Specifically, can the Committee draw out any conclusions from the recent *in vitro* study (Zimmerman *et al*., 2020) to prove useful towards a risk assessment?
iii) Which biobased materials would the Committee like to prioritise to review in further detail? Or would the Committee wish the Secretariat to come up with a prioritisation list based on information available?
iv) Would the Committee like to review any other aspects such as emerging technologies used in food packaging *i.e.* intelligent packaging?
v) Does the Committee have any other comments?

Secretariat

October 2020

Abbreviations

BBFCMs	bio-based food contact materials
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
FERA	Food and Environment Research Agency
FSA	Food Standards Agency
ISO	International Organization for Standardization
PA	polyamide
PBAT	polybutylene adipate terephthalate
PE	polyethylene
PEF	polyethylene furanoate
PET	polyethylene terephthalate
PHA	polyhydroxyalkanoates
PLA	polylactic acid
PP	polypropylene
PTT	polytrimethylene terephthalate
SEM	scanning electron microscopy

References

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This is a background paper for discussion.
It does not reflect the views of the Committee and should not be cited.

TOX/2020/52 ANNEX A

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

FERA Report: Bio-based materials for use in food contact applications (PDF)

fera

Bio-Based Materials For Use In Food Contact Applications

Fera project number FR/001658

Report to the Food Standards Agency

June 2019

By: Graham Bonwick, Emma Bradley, Ioana Lock and Rosario Romero

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Internal Tools at the FSA

Internal FSA tool developed in house by data scientists is helping us learn about potential and emerging food safety and fraud issues by using machine learning algorithms to extract and summarise risks with commodity, country and hazard, by accessing various data sources (including various official data sources and news websites).

An example is shown below of the bamboo outcomes:

Figure 1. Number of alerts concerning a hazard

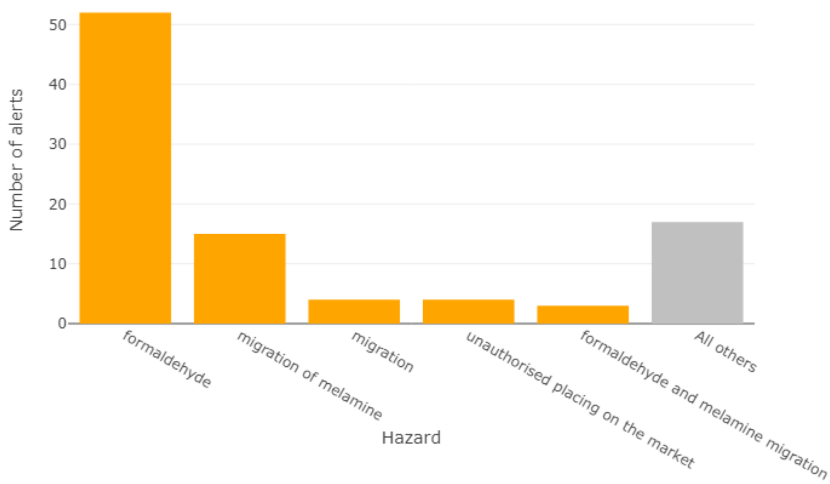

Figure 2. Number of alerts concerning product